

MAR - 8 2004

**XIV. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA. (Separate Page)**

A: Submitter: Dr. Samuel Waknine, President, DRM Research Laboratories, Inc., Branford, CT 06405.

I. Classification Name and Number: Endosseous Implant (76DZE),

II. Common/Usual Name: Dental Implant, Endosseous, Post (or screw)-type, titanium or titanium alloy.

III. Proprietary Name: ZTI Implants System

IV. Classification: This device is being finally classified by the Dental Devices Panel (Title 21 CFR 872.3640.

V. Performance standards: None applicable. Materials meet ASTM voluntary standards

VI. Description: The ZTI Implants System implants are post-type endosseous dental implants with design and manufacturing concepts, materials, surgical procedures, and intended uses quite similar to the preamendment device and to others rated substantially equivalent to the preamendment device. The ZTI Implants system is most similar to the Straumann ITI Implants System which received concurrence of substantial equivalence from the Food and Drug Administration in premarket notification submission K-955281 and the ITI TE™ system in general. Like many commercial implants, the ZTI devices are manufactured of high-purity (99+%) titanium, or titanium alloy (ASTM F 136-84 titanium - 6 aluminum - 4 vanadium)..

ZTI Implants also are available in coated form, either hydroxyapatite or titanium plasma spray. These devices are equivalent to various coated endosseous implants on the market, for example the Sabertech implants of Genentech, Inc., which were cleared under K-924112 and the Crystal-Seal Implants of Crystal Technology, cleared under K-980447.

VII. Labels and Instructions for Use are provided, as are labels for competitive products.

VIII. Intended Use: These devices are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices and to restore the patient's chewing function.

VII. Substantial Equivalence: This device is equivalent to devices manufactured and sold before 1976, having a U. S. classification number of 76 DZE, and those described under 21 CFR 872.3640. It is also equivalent to several devices currently on the market that have been determined by the FDA to be substantially equivalent to the above preamendment devices, particularly to the Straumann ITI TE system cleared under K-955281. Some examples of other equivalent products are:

Driskell Bioengineering, Westerville, OH, K-853788, DB Precision Implant  
Steri-Oss (Subs. Denar, Anaheim, CA.), Denar Dental Implant,  
K-852802; Steri-Oss Implant, K-884845.  
Stryker Instruments, Kalamazoo, MI, K-921805, Stryker Precision System.In

VIII. Clinical Discussion and Brief Literature Review: Endosseous implants, and especially those of titanium or titanium alloy, in the "post" or "screw" configuration, have been proved safe and effective through the years. The possible adverse effects summarized in this 510(k) cover those listed by the United States classification panel [Federal Register, vol. 45, No. 251, pp 86025-6, Dec. 30, 1980], as well as to those revealed in a recent literature search. Matukas, "Medical Risks Associated with Dental Implants," states, "Little or no hard data could be found on the medical risks associated with [dental] implants." Because of the wide-spread usage of dental implants, Smith and Zarb made a careful review of the literature and proposed criteria for implant success.

A thorough computerized Medline literature search produced over 700 review articles. The Journal of Dental Education published a special issue "Proceedings of the Consensus Development Conference on Dental Implants [National Institutes of Health, Bethesda, MD, June 13-15, 1988], Vol. 52, No. 12, pp. 677-831, Dec. 1988. This added to the literature search above, with some especially pertinent reprints from the scientific literature, provide a comprehensive summary of available scientific data.

Zarb completed his report of the detailed Toronto 10-year study by concluding that "the tried and tested Branemark implant technique has revolutionized the treatment options open to the prosthodontist. For the edentulous patient...the prospect for a lifetime of restored oral comfort, function, and appearance have now become predictable and reliable." These results are ample evidence of the safety and effectiveness of these endosseous implants.

END OF 510(k) SUMMARY



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR - 8 2004

Dr. Samuel Waknine  
President  
DRM Research Laboratories, Incorporated  
29 Business Park Drive  
Branford, Connecticut 06405

Re: K034067  
Trade/Device Name: ZTI Implant System™ DRM Implant  
Regulation Number: 872.3640  
Regulation Name: Endosseous Implant  
Regulatory Class: III  
Product Code: DZE  
Dated: February 23, 2004  
Received: March 3, 2004

Dear Mr. Waknine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number): K034067

Device Name: ZTI Implants System™

### Indications for Use:

The permanent post-type implants of this system are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.

The temporary implants are intended to provide immediate transitional splinting stability or fixation of new or existing crown, bridge and denture installations in partially or fully edentulous patients. It is indicated for a maximum of one year.

Prescription Use  AND/OR  
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



\_\_\_\_\_  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number: K034067

Page 1 of \_\_\_\_\_